

REMARKS

In the Office Action dated March 10, 2004, claims 1-4 and 7-12 were rejected under 35 U.S.C. §103(a) as being unpatentable over Ward et al. in view of Olsson et al.. Claims 6, 14 and 15 were rejected under 35 U.S.C. §103(a) as being unpatentable over Ward et al. and Olsson et al., further in view of Sinderby.

The rejections are respectfully traversed for the following reasons.

In the method and apparatus disclosed and claimed in the present application, an excitable cell signal is obtained from a patient being provided with breathing assistance that is exclusively pneumatic breathing assistance, and this excitable cell signal, in combination with a second respiration indicator signal based on the measured excitable cell signal, is used to adapt a trigger requirement in the exclusively pneumatic breathing assistance.

In the Ward et al. reference, the breathing detector 18 can receive intrinsic nerve impulses from the patient, such as from the phrenic nerve. These signals that are indicative of breathing, however, are not used in the Ward et al. reference to change any of the basic ventilator settings relating to pneumatic breathing assistance. Instead, the detection of the aforementioned breathing signals is used in the Ward et al. reference to *augment*, as necessary, the pneumatic ventilation that takes place using the ventilator 6. This pneumatic ventilation is augmented, as necessary, with muscle stimulation provided by a muscle stimulation apparatus 14. As explicitly stated in the paragraph at column 5, lines 58-63 in Ward et al., as long as adequate breathing signals are detected, these signals are used to synchronize operation of the ventilator 6. There is no disclosure or suggestion anywhere in the Ward et al. reference that a signal from the phrenic nerve is used to set or adjust a

trigger level in the context of the ventilation that occurs using the ventilator 6. In other words, in the Ward et al. reference, as long as signals are received from the phrenic nerve that are indicative of “normal” breathing, nothing changes. The signal from the phrenic nerve is used in the Ward et al. reference to cause a *change* in the breathing assistance only under certain circumstances, and this change does not involve any change whatsoever in the pneumatic breathing assistance provided by the ventilator 6. The only change that occurs dependent on the signal from the phrenic nerve is that additional assistance is provided by means of a muscle stimulation apparatus 14. This is explained in detail at column 6, lines 1-13 of the Ward et al. reference.

Independent claims 1 and 8 have been amended to make clear that the breathing assistance involved in those claims is exclusively pneumatic breathing assistance, and those of ordinary skill in this technology understand that pneumatic breathing assistance does not include breathing assistance by nerve stimulation, but instead involves breathing assistance only by adjusting pressure and flow of the breathing gas.

As noted above, it is explicitly clear from the Ward et al. reference that the signal from the phrenic nerve is not used in any manner to alter the pneumatic breathing assistance that is provided by the Ward et al. system, but is used only, under certain circumstances to *augment* that pneumatic breathing assistance by the additional technique of muscle stimulation.

The Examiner acknowledged that the Ward et al. reference does not disclose the use of a control unit and a comparator as set forth in the present claims, but relied on the Olsson et al. reference as providing such teachings. The reason why

the Ward et al. reference does not disclose or suggest such a control unit or a comparator is clear from the above discussion. In the Ward et al. system, the pneumatic breathing assistance proceeds in a conventional manner, and therefore there is no need in the Ward et al. reference to discuss details of how that conventional pneumatic breathing assistance occurs. The departure from conventionally operating breathing assistance systems disclosed in the Ward et al. reference involves the aforementioned *augmentation* of this conventional pneumatic ventilation with, under appropriate circumstances, muscle stimulation. In the context of such muscle stimulation, it is simply either provided or not provided, dependent on the signal detected from the phrenic nerve. There is thus no need for any detailed control steps or comparison steps with regard to analysis of, or making use of, the signal detected from the phrenic nerve.

Since the Ward et al. reference does not include any suggestion whatsoever to employ a control circuit or a comparator (of any type) for making use of the signal detected from the phrenic nerve, and since the Olsson et al. reference discloses a control circuit and a comparator used exclusively for the control of pneumatic ventilation, if a person of ordinary skill in this field, without having first the benefit of reading the present disclosure, were to modify the Ward et al. reference in accordance with the teachings of Olsson et al., such a person would merely use the control circuitry disclosed in the Olsson et al. reference for controlling the pneumatic ventilation in Ward et al., but would find no basis or guidance in either of those references for using the control circuit disclosed in the Olsson et al. reference for any purpose involving analysis of, or use of, the signal detected from the phrenic nerve.

More specifically, there is no teaching or suggestion in either of the Ward et al. or Olsson et al. references to make use of the control circuitry disclosed in the Olsson et al. reference for the purpose of setting a trigger level based on an excitable cell signal, in combination with another signal derived from that excitable cell signal, for controlling pneumatic ventilation. The control circuitry disclosed in the Olsson et al. reference is not needed in the context of the Ward et al. system for interacting in any way with the signal received from the phrenic nerve, because the only use made in the Ward et al. system of the signal from the phrenic nerve is to make a “yes” or “no” determination as to whether augmentation of the pneumatic ventilation by the additional technique of muscle stimulation should be employed. Since there is no trigger level that must be used in making this “yes” or “no” determination in the Ward et al. system, there is no need to set or adjust such a (non-existent) trigger level.

Dependent claims 3, 4, 7 and 9-12 add further structure to the non-obvious method of independent claim 1 or the non-obvious apparatus of independent claim 8, and are therefore patentable over the teachings of Ward et al. and Olsson et al. for the same reasons discussed above in connection with those independent claims.

As to the rejection of claims 6, 14 and 15 under 35 U.S.C. §103(a) based on Ward et al. and Olsson et al., further in view of Sinderby, for the above reasons Applicant submits that further modifying the Ward et al./Olsson et al. combination in view of the teachings Sinderby still would not result in the subject matter of claim 6 (which embodies the subject matter of claim 1 therein) nor the subject matter of claims 14 or 15 (which embody the subject matter of claim 8 therein).

All claims of the application are therefore submitted to be in condition for allowance, and early reconsideration of the application is respectfully requested.

Submitted by,

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